

REMARKS

Favorable reconsideration of this application, in light of the preceding amendments and following remarks, is respectfully requested.

Claims 1-17 are pending in this application.

Information Disclosure Statement

Applicants thank the Examiner for indicating that the references submitted in the Information Disclosure Statement filed on August 16, 2006, have been considered.

Foreign Priority

Applicants note with appreciation the Examiner's acknowledgement that certified copies of priority documents have been received by the U.S.P.T.O. However, the Examiner has not indicated if all the priority documents have been received. Applicants therefore respectfully request the Examiner to indicate if all priority documents have been received by the office in the next office communication.

Drawings

Applicants also respectfully note the present action indicates that the drawings have been accepted by the Examiner.

Rejections under 35 U.S.C. § 112

Claims 3, 8, 10-11, 13, and 16 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Although the Applicants do not necessarily agree with the Examiner, Applicants have amended the claims taking into consideration the Examiner's Comments.

The Applicants, therefore, respectfully request reconsideration and withdrawal of the rejection to claims 3, 8, 10-11, 13, and 16 under 35 U.S.C. § 112, second paragraph.

Rejections under 35 U.S.C. § 101

Claims 1-17 stand rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter. Applicants respectfully traverse this rejection for the reasons detailed below.

As the Examiner is likely aware, the Court of Appeals for the Federal Circuit (CAFC) issued a decision in *In re Bilski* which addresses the test for patent-eligible processes within the meaning of 35 U.S.C. § 101. The decision in *Bilski* re-affirmed the tests set forth by the Supreme Court in *Diamond v. Diehr*, 450 U.S. 175 (1981). Namely, the CAFC in *Bilski* stated that "[a] claimed process is surely patent-eligible under § 101 if:

- (1) it is tied to a particular machine or apparatus, or
- (2) it transforms a particular article into a different state or thing.

Claim 1 recites:

A method for selecting a potential participant for a medical study based on a selection criterion, the method comprising:
 assigning a first search criterion to the selection criterion based on the medical study;
 assigning a second search criterion to the selection criterion based on the medical study and distinct from the first search criterion;
 evaluating, *using a processor*, patient data stored in a *database* using the second search criterion;
 determining, *by the processor* and based on the evaluation of the patient data, a measure for fulfilling the selection criterion for a patient associated with the patient data based on the second search criterion; and
 selecting the patient as a potential participant for the medical study based on the determined measure.

As the Examiner will appreciate, claim 1 is indeed tied to a particular machine or apparatus namely “*a processor*,” and “*a database*.” Therefore, the method of claim 1 is statutory subject matter eligible. Claims 2-17 are statutory at least for being dependent upon a statutory base claim.

The Applicants, therefore, respectfully request reconsideration and withdrawal of the rejection to claims 1-17 under 35 U.S.C. § 101.

Rejections under 35 U.S.C. § 102

Claims 1-17 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. Pub. No. 2002/0077853 to Boru et al. (“Boru”). Applicants respectfully traverse this rejection for the reasons detailed below.

The Examiner asserts that the method of selecting a clinical trial as disclosed by Boru teaches the claimed method for “selecting a potential

participant for a medical study,” as recited by claim 1. Applicants respectfully disagree.

Boru teaches facilitatating identification of the most appropriate clinical trials by employing the "Exclusionary Criteria" already listed in the public clinicaltrials.gov site. The system searches a database of clinical studies, such as the clinicaltrials.gov database, to find the trials specific to a particular disease. All of the clinical trials in the disease-specific area are then extracted from the database. Next, all of the “exclusionary criteria” listed in each trial are then identified and extracted. After identifying all of the criteria cumulatively across all of the clinical trials, a list is made of the criteria having the most redundancy, i.e., the criteria that are common to a predetermined number of the trials. See Boru paragraphs [0017]-[0020].

Boru does not teach or fairly suggest **“selecting the patient as a potential participant for the medical study** based on the determined measure,” as required by claim 1. By contrast, Boru teaches a system and method for use by a physician and a patient to create a list of clinical studies the patient may be suited for. The search results in a list of a few remaining studies applicable to the special patient. One of the studies can then be selected for the patient. The method described by Boru is the exact opposite of what is claimed by claim 1.

Further, Boru teaches the selection of a single "Exclusionary Criteria" based on choosing “common categories” into which similar criteria, although having different English language descriptions, may be sorted. Boru teaches that there may be some ambiguity in the searchable data, and that the

physician may have to modify the search term. However, the modified search term is just the original term reworded. See Boru paragraph [0038]. Boru does not teach or fairly suggest “**assigning a first search criterion** to the selection criterion based on the medical study” **and** “**assigning a second search criterion** to the selection criterion based on the medical study and **distinct from the first search criterion,**” as required by claim 1. By contrast, Boru teaches finding a few exclusion criteria which are common to possibly all or most of the studies in the clinicaltrials.gov database and to summarize these criteria in a short check list. The physician fills in the answers to the check list for the special patient. The search results in a list of a few remaining studies applicable to the special patient. One of the studies can then be selected for the patient.

Because Boru does not teach each and every limitation of claim 1, Boru does not anticipate or render claim 1 obvious. Claims 2-17 are patentable at least by virtue of their dependency from claim 1.

The Applicants, therefore, respectfully request reconsideration and withdrawal of the rejection to claims 1-17 under 35 U.S.C. § 102(b).

CONCLUSION

In view of the above remarks and amendments, the Applicants respectfully submit that each of the pending objections and rejections has been addressed and overcome, placing the present application in condition for allowance. A notice to that effect is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to contact the undersigned.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

HARNESS, DICKEY, & PIERCE, P.L.C.

By



Donald J. Daley, Reg. No. 34,313

P.O. Box 8910
Reston, Virginia 20195
(703) 668-8000

DJD/⁴⁵EPS:has